Nucletron

NOV - 9 2005

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

K052228

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	Smit Sleeve
Common/Usual Name:	Remote Afterloading for Intracavitary Brachytherapy applications
Classification Name:	Remote controlled radionuclide applicator system accessory
Classification:	21Cfr892.5700 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Miami Vaginal Applicator Set	K953946

Description:

The Nucletron Smit Sleeve as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment and is intended for Intracavitary Brachytherapy procedures.

The Smit Sleeve has a Flange, which is sutured against the cervix. The Smit Sleeve prevents that the Intrauterine Tube of the Gynaecological Applicator is inserted to deep in the Uterus.

K052227

The Smit Sleeve is left in the patient between fractions. Between fractions the Intrauterine Tube of the Gynaecological Applicator can be inserted into the endometrium multiple times without dilating the Cervix. After the treatment the Smit Sleeve is removed.

The device uses similar (implantable) materials as in the legally marketed predicate device cited the Intracavitary Mould. The device uses similar implant techniques respect to the legally marketed predicate device cited the Miami Vaginal Applicator Set.

The Smit Sleeve is used as an accessory to the Nucletron microSelectron.

Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

The Smit Sleeve is intended for Intracavitary Brachytherapy procedures involving Nucletron remote afterloading equipment.

Summary of technological considerations:

The Smit Sleeve is substantially equivalent to the cleared predicate device, Miami Vaginal Applicator Set, 510(k)#: K953946.

Name: Frits van Krieken
Title: Business Segment Manager
Nucletron B.V.
Veenendaal, The Netherlands

8 June 2005
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nucletron Corporation
% Elizabeth Rosenfeld
Administrative Coordinator
KEMA Quality B.V./KEMA Medical
4377 Country Line Road
CHALFONT PA 18914

Re.: K052228
Trade/Device Name: Smit Sleeve
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system.
Regulatory Class: II
Product Code: JAQ
Dated: November 2, 2005
Received: November 3, 2005

Dear Ms. Rosenfeld:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS)

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number	K052228
Device Name	Smit Sleeve
Indications for Use	The Smit Sleeve is intended for Intracavitary Brachytherapy procedures involving Nucletron remote afterloading equipment. The Smit Sleeve (189.660 to 189.667) is an accessory to the GYN Applicators and the CT/MR Smit Sleeve (189.565) is an accessory to the CT/MR GYN Applicators.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052228